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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,415

Applicant(s)

FISH, FALK

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-10 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 13, 2005 has been entered.

Amendment Entry

2. The amendment filed May 13, 2005 has been entered. Claims 2-3, 11 and 13-14 have been cancelled. Claims 6 and 9-10 have been amended. Claims 1, 4-10 and 12 are under consideration.

Allowable Subject Matter

3. The indicated allowability of claims 1 and 4-5 is withdrawn in view of the newly discovered objections and rejections.

Withdrawal of Rejections

4. The following rejections were withdrawn in view of applicants' amendments and arguments:

- a) The rejection of claim 9 under 35 U.S.C. 112, second paragraph;
- b) The rejection of claim 10 under 35 U.S.C. 102(b) as being anticipated by Paisey et al; and
- c) The rejection of claims 6-8 and 12 under 35 U.S.C. 103(a) as being unpatentable over Paisey et al., in view of Sigma Chemical Company Catalog 1992.

Response to Arguments

5. Applicants' arguments filed May 13, 2005 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Paisey et al., in view of Albarella et al., (US Patent 5,089,420) is maintained for reasons already of record. The rejection was on the grounds that it would have been prima facie obvious at the time of applicants' invention to modify a kit which includes a means for obtaining a hair sample; a means for measuring the level of hemoglobin; a means for measuring the level of glucose; and a means for calculation wherein the modification comprises using an alternative and functionally equivalent measuring means such as a color detecting test strip to also measure hemoglobin and glucose.

Applicants' urge that Albarella et al., is unrelated to the instant claims, since Albarella et al., measure hemoglobin using amine borate compounds to detect occult blood in urine.

However, the disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not

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become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132. Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims since the prior art device has the recited components. Moreover, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Therefore, applicants' argument that the instant kit has a different purpose is not persuasive, since the instant kit claim does not become patentable simply because applicants' have described the kit as having a different purpose; especially in view of the fact that the prior art references teach a kit comprising means which meet the limitations of the claim.

Applicants' assert that one measuring fetal and glycosylated hemoglobin in a blood sample would not be motivated to combine this with a method for detecting occult blood in urine in order to measure glucose and a blood component.

The MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). Likewise, the fact that Paisey et al., in view of Albarella et al., teach other uses for the kit does not preclude them from teaching a kit comprising the same instantly recited components.

Moreover, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is

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capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). There are no structural differences between the claimed means for obtaining a hair sample; means for measuring the level of hemoglobin; means for measuring the level of glucose; and a means for calculation and the means disclosed by the prior art. Therefore applicants' arguments are not persuasive and the rejection is maintained.

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one would have a reasonable expectation of success by incorporating a test strip which was already known in the art to colorimetrically measure hemoglobin and glucose. Moreover, no more than routine skill would have been required to use an alternative and functionally equivalent means for measuring the level of glucose in the obtained sample, since only the expected results would have been obtained. Therefore, the use of alternative and functionally equivalent measuring means would have been desirable to those of ordinary skill in the art based on the known ability, ease and efficiency for measuring glucose.

New Grounds of Objection and Rejection

Claim Objections

7. Claims 1 and 4 are objected to because of the following informalities: the misspells hemoglobin as "hemoglobinin". Claim 4(iii) refers to "andinterstitial" which should be "and interstitial." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 4-5, 7-10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 1 recites the limitation "the tested individual." There is insufficient antecedent basis for this limitation in the claim.

b) Claim 5 recites the limitation "the hair follicle." There is insufficient antecedent basis for this limitation in the claim.

c) Claim 10 recites the limitation "the obtained body sample." There is insufficient antecedent basis for this limitation in the claim.

e) Dependant claims 4-5, 7-10 and 12 refer to "A method" or "A kit", however the suggested claim language is to use of the article "The." Therefore the suggested claim language is "The method according to..." or "The kit according to...."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Albarella et al. (US Patent 5,089,420 published February 18, 1992). The claims are drawn to a kit comprising a means for obtaining a urine sample; a means for measuring the level of hemoglobin; a means for measuring the level of glucose; a means for calculating the level of glucose and a test strip.

Albarella et al., (US Patent 4,017,261) teach a test device for determining the presence or concentration of a peroxidatively active substance in a urine test sample (col. 1, lines 8-13). Peroxidase and pseudoperoxidase substances include glucose and hemoglobin (col. 1 lines 35-45). The analysis of urine for glucose occurs because glucose oxidase converts the glucose in urine to another testable compound (col. 1 lines 46-49). And the peroxidase enzyme, which is also present in the assay, will catalyze a dye compound which results in a color transition that ultimately correlates to the original concentration of glucose in the urine sample (col. 1, lines 49-61). Similarly, a peroxidatively active substance like hemoglobin can catalyze an interaction comprising an oxidizable dye compound (col. 1, lines 62-64). The resulting interaction provides a color transition or detectable response which is indicative of the presence and concentration of the peroxidatively active substance (col. 2, lines 2-6). Thus, Albarella

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et al., teach a means for obtaining a urine sample, a means for measuring the level of hemoglobin; a means for measuring the level of glucose and a calculation means. Test strips have been used in assays for detecting peroxidately active substances (col. 3, lines 60-63). The test strip can provide qualitative or quantitative measurements of hemoglobin and glucose (col. 11 lines 15-30). The device includes a test pad comprising a suitable carrier matrix incorporating an indicator reagent composition capable of interacting with the test sample components to produce a detectable response (col. 8 lines 63-66). The response can be a visually detectable response or is detectable by an instrument (col. 8-9 lines 66-2). The test strip can be analyzed using an instrument into which the test strip can be inserted in such as a spectrophotometer or colorimeter to precisely determine the degree of color transition (col. 28 lines 25-30).

It is noted that the components in a kit are commercially available. The reference specifically disclose a device for use in a kit, therefore inherent in this disclosure is a kit comprising the recited components to determine the level of glucose in a sample which also achieves economic efficiency and ease in testing.

Therefore, Albarella et al, teach a kit comprising a means for obtaining a urine sample; a means for measuring the level of hemoglobin; a means for measuring the level of glucose; a means for calculating the level of glucose and a test strip just as instantly claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albarella et al. (US Patent 5,089,420 published February 18, 1992) and Svoboda et al., (US Patent 4,017, 261 published April 12, 1977). The claims are drawn to a kit comprising a means for obtaining a urine sample; a means for measuring the level of hemoglobin; a separation means; a means for lysing red blood cells; a means for measuring the level of glucose; a means for calculating the level of glucose and a test strip.

Albarella et al., has been discussed above, however Albarella et al., do not disclose a separation means or a means for lysing red blood cells.

Svoboda et al., teach diagnostic test strips suitable for rapid detection and semi-quantitative estimation of erythrocytes and hemoglobin in urine (col. 1, lines 35-38). The test strips detect the peroxidase activity of hemoglobin to determine the amount of hemoglobin present (col. 2, lines 35-40). Other reagents used to perform the assay include buffers comprising ammonium salts (col. 3 lines 33-36). Ammonium salts are known for their ability to lysis red blood cells, thus Svoboda et al., teach a means for lysis red blood cells.

It is noted that the components in a kit are commercially available. The reference specifically disclose a device for use in a kit, thus it is obvious to any one of ordinary skill in the art to create a kit comprising the recited components to determine the level of glucose in a sample.

Therefore, it would have been prima facie obvious at the time of applicants' invention to modify a kit which includes a means for obtaining a urine sample; a means for measuring the level of blood components; a means for measuring the level of hemoglobin and glucose; and a means for calculation wherein the modification comprises using additional buffers to lysis red blood cells, as taught by Svoboda et al. In this case, one would have a reasonable expectation of success by incorporating a means for lysing red blood cells since it is known in the art that hemoglobin is found within the red blood cell and lysis is a logical way to release the hemoglobin. Moreover, no more than routine skill would have been required to use an alternative and functionally equivalent means of obtaining hemoglobin to test since only the expected results would have been obtained and those results would have been desirable to those of ordinary skill in the art based on the known ability of measure glucose and hemoglobin.

11. Claims 6-7 and 9-10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Albarella et al. (US Patent 5,089,420 published February 18, 1992) in view of Paisey et al., (published in 1984). The claims are drawn to a kit comprising: a means for obtaining a hair removal means; a diluent in which the blood is obtained; a means for

measuring the level of a blood component; a means for measuring the level of glucose; and a means for calculating the level of glucose.

Albarella et al., has been discussed above, however Albarella et al., do not disclose a means for obtaining a hair removal means; a diluent in which the blood is obtained.

Paisey et al., teach glycosylation of hair and the measure of chronic hyperglycaemia. The authors took hair samples from patients (page 670). Therefore Paisey et al., teach a means for obtaining hair samples. The patients also had blood taken for measurement of hemoglobin (page 670). Paisey et al., teach a separation step that lyses the red blood cells in order to release the analyte to be tested. Also the authors inherently teach separation of red blood cells from the blood sample in order to determine the glycosylated hemoglobin concentration (page 669). A means for measuring the level of a blood component such as hemoglobin in the sample was achieved by agar gel electrophoresis (page 670). A means for calculating the level of glucose in the blood of the sample was based on the statistical results achieved by evaluating statistical differences and regression analysis (page 670).

It is noted that the components in a kit are commercially available which eliminates the variability that can occur when performing the assay. Although the reference does not specifically disclose a kit, it is obvious to one of ordinary skill in the art to create a kit comprising the recited components to determine the level of glucose in a sample and achieve economic efficiency.

It is noted that the components in a kit are commercially available. The reference specifically disclose a device for use in a kit, thus it is obvious to any one of ordinary skill in the art to create a kit comprising the recited components to determine the level of glucose in a sample and achieve economic efficiency.

Thus, it would have been prima facie obvious at the time of applicants' invention to modify the kit of Albarella et al., to obtain a sample from hair and use a diluent to contain the collected hair and blood as taught by Paisey et al. No more than routine skill is involved on adjusting a particular starting material in order to achieve the results already taught in the prior art. Moreover, no more than routine skill would have been required to use an alternative and functionally equivalent sample and diluent, since only the expected results would have been obtained; thus the use of alternative and functionally equivalent sample and diluent would have been desirable to those of ordinary skill in the art based on the known ability to detect hemoglobin concentrations in hair. Additionally, one of ordinary skill in the art would have a reasonable expectation of success since the prior art already teach kit components to measure hemoglobin and glucose and Paisey et al., only teach using additional sample types to analyze those same components.

Conclusion

12. No claims allowed.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines



July 20, 2005